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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,933	02/27/2002	Peter Sondermann	HUBR-1189(10	7771

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,933	SONDERMANN ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *81, 83-86, 93 -98* is/are pending in the application.

4a) Of the above claim(s) *95-98* is/are withdrawn from consideration.

5)☒ Claim(s) *81 and 83* is/are allowed.

6)☒ Claim(s) *84-86 and 93-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 1/27/05 is acknowledged.

Claims 81, 83-86, 93 -98 are pending.

2. Newly submitted claims 95-98 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The elected Group III, claims 81-86 and 91-94, now claims 81, 83-86 and 93-94 drawn to a homologenous preparation of recombinant soluble receptor of SEQ ID NO:3. Newly submitted claims 95-98 drawn to a prokaryotic expression vector comprising nucleic acid molecule. These invention are different with regards to their structure, physical and chemical properties and mode of action which require non-coextensive searches; therefore each product is patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 95-98 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 81, 83-86 and 93-94 reads on homogenous preparation of recombinant soluble FcγRIIb receptor wherein said receptor contains SEQ ID NO:3 and pharmaceutical composition comprises said homogenous preparation of recombinant soluble FcγRIIb receptor , under consideration in the instant application.

3 . Applicant's amendment filed 01/27/05 in conjunction with Declaration of Jacob under 37 C.F.R 1.132 demonstrating the effectiveness of pharmaceutical composition containing a recombinant soluble FcγR11b receptor of SEQ ID NO:3 to treat EAE and AIA in the mice, has obviated the previous rejection under 35 U.S.C. 112, first paragraph with regards to enablement and written description of a homogenous preparation of recombinant soluble FcγRIIb receptor wherein said receptor contains SEQ ID NO:3 and a pharmaceutical composition comprising said preparation for use in treatment of multiple scleroses (MS) and rheumatoid arthritis (RA); and rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,623,053 or US Patent 6,675,105.

In view of the amendment, filed 01/27/05 the following rejection remains:

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 84-86 and 93-94 stand rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment multiple scleroses (MS) and rheumatoid arthritis (RA) does not reasonably provide enablement for: (i) a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment or prevention any autoimmune diseases, allergies or tumor diseases, as claimed in claims 84-85, or (ii) a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment of AIDS or multiple myeloma as claimed in claim 86 for the same reasons set forth in the previous Office Action, mailed 08/25/04.

Applicant's arguments, filed 08/25/04 have been fully considered, but have not been found convincing.

Applicant asserts that attached declaration by co-inventor Dr. Uwe Jacob provided the pharmaceutical efficacy of the claimed FcγRII receptor in animal models.

Contrary to Applicant's assertion, it is noted that Declaration by Dr. Uwe Jacob provided support for the use of a pharmaceutical composition in the treatment of MS and RA, using mice models. As has been discussed in the previous Office Action, the specification does not adequately teach a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment or prevention any autoimmune diseases, allergies or tumor diseases, as claimed in claims 84-85, or (ii) a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment of AIDS or multiple myeloma as claimed in claim 86. Moreover, no animals models were used to study the effectively of treatment any autoimmune diseases, allergies or tumor diseases, including AIDS, or multiple myeloma using disclosed recombinant soluble FcγRIIb receptor wherein said receptor contains amino acid sequence of SEQ ID NO:3 . In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the preparation and pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed preparation and pharmaceutical composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success. Feldman et al (Transplant. Proc. 1998, 30, 4126-4127) teach that "while it is not difficult to study the

pathogenesis of animal models of disease, there are multiple constraints on analyses of the pathogenesis of human disease, leading to interesting dilemmas such as how much can we rely on and extrapolate from animal models in disease". In addition, Cochlovius et al (Modern Drug Discovery, 2003, pages 33-38) teach that in contrast to in vitro models, and partly animal-human xenograft systems, tissue cells in vivo seems to express molecules for defense against cellular immune systems as well as against complement. Although these defense mechanisms are still poorly understood, they provide some hints as to why many potential therapeutics perform marvelously in vitro but a fairly high portion of them still fail in vivo. Feldman et al . further teach that in a chronic immune-driven inflammatory response there are a number of pathways that become engaged and effective therapy in immune inflammatory diseases such as rheumatoid arthritis, will come from therapy aimed at several points in the disease pathway. Moreover, Aoki et al (US Patent 5,470,578) teach that the cause of a chronic multiple inflammatory disease, rheumatoid arthritis, is still unknown and no reliable treatment of the disease has been established (see entire document, column 1, lines 55-60 in particular).

Also the issues is that the burden of enabling the prevention of a disease (i. e. the need for additional testing) would be greater than that of enabling a treatment due to the need to screen those humans susceptible to such diseases and the difficulty of proof that the administration of the drug was the agent that acted to prevent the condition. Further, the specification does not provide guidance as to how one skilled in the art would go about screening those patients susceptible to autoimmune diseases, allergies or tumor diseases, including HIV infection and AIDS within the scope of the presently claimed invention. Nor is guidance provided as to a specific protocol to be utilized in order to prove the efficacy of the presently claimed compounds in preventing these disease states. Declaration by Dr. Uwe Jacob only provided support for the use of a pharmaceutical composition in the treatment of MS and RA, using mice models. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment or prevention any autoimmune diseases, allergies or tumor diseases, as claimed in claims 84-85, or (ii) a pharmaceutical composition comprising a homogenous preparation of recombinant soluble FcγRII b receptor of SEQ ID NO:3 for use in treatment of AIDS or multiple myeloma as claimed in claim 86 in manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Claims 81 and 83 are allowed.

7. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 28, 2005

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